

Remarks

Claims 1-32 are pending in the subject application. Applicants acknowledge that claims 29-32 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 1, 25 and 28. Support for the amendments can be found throughout the subject specification and in the claims as originally filed (see, for example, pages 4-8). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-32 are currently before the Examiner and claims 1-28 are currently under examination. Favorable consideration of the pending claims is respectfully requested.

The application was filed with Figures 1-3. The Office Action Summary page did not indicate that the drawings were accepted or objected to by the Examiner. Applicants respectfully request that the Examiner consider the figures and indicate their status in the next communication.

Submitted herewith is a supplemental Information Disclosure Statement (IDS), accompanied by the form PTO/SB/08, and a copy of the references listed therein. Applicants request that the references in the IDS be made of record in the subject application.

Applicants also request the courtesy of an interview to discuss the rejection of record in this matter at the time this response is considered.

The disclosure is objected to because of informalities. The Office Action indicates that there is a typographical error on page 1, line 23 of the specification. The Office Action also notes that specification contains an embedded hyperlink and/or other form of browser-executable code. Applicants respectfully submit that these issues are moot in view of the amendments made to the specification. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 1-28 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Office Action asserts that claim 1 recites "recycling a solid support" for "cultivation of anchorage-dependent cells" which is "within a system for cell cultivation". The Office Action indicates that the language is unclear as to whether cells or a cell-cultured substrate are required of the method or if they are merely exemplary. The Office Action also states that claim 1 does not recite any required sequence or a conclusion of a recycled support and thus it is also unclear if the recited steps provide said recycled solid support or if another product of the method or another method is intended. In this

regard, Applicants respectfully submit that the amendments made to claim 1 have rendered this issue moot and that the method is clearly directed to recycling a solid support contained within a system for culturing anchorage-dependent cells and upon which anchorage-dependent cells had been previously affixed (see pages 11-16 of the as-filed description).

The Office Action also indicates that claim 1 recites “rinsing” the system with “aqueous solution” and with “sodium hydroxide solution” and it is unclear whether the same rinsing step and solution is used for all 3 steps (b), (c), and/or (d). The Office Action asserts that claim 25 recites the phrases “about 50°C to about 70 minutes” and “about 55°C to about 65°C minutes” and it is unclear if a temperature or temporal unit is intended. Applicants thank the Examiner for the careful review of the claims and respectfully submit that the amendments submitted herewith have rendered this issue moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 1-28 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action states that the specification is enabled for recycling a solid support for cultivation of a CHO anchorage-dependent cell, wherein the solid support comprises a polymer selected from polyester and polypropylene, but is not enabled for all materials and all cells. Applicants respectfully assert that the claims as filed are enabled.

When rejecting a claim under the enablement requirement of section 112, the examiner bears the “initial burden of setting forth a reasonable explanation as to why [he/she] believes that the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification.” *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Thus, the examiner must provide evidence or technical reasoning substantiating those doubts (*Id.*; and M.P.E.P. § 2164.04). In the case of this particular point of rejection, it is respectfully submitted that the Office Action has failed to set forth any objective evidence which establishes that the claims are not enabled.

The Office Action argues that the claims, taken together with the specification, imply a breadth that is greater than that supported by the disclosure. The Office Action also argues that the state of the art “is such that culturing cells with a variety of supports and cells is known; however, the re-use/recycling of such supports/materials and the cells capable of cultivation thereupon was

unresolved at the time of the instant invention”. In support of this argument, the Office Action relies on Frequently Asked Questions (FAQ) from the NBSC.com web site. However, Applicants note that the cited document indicates that the reuse of Fibra-Cel disks is not recommended. There is no teaching that the disks cannot be reused/recycled and there is no teaching that the reuse/recycling of support materials, such as Fibra-Cel disks, cannot be performed. Indeed, the as-filed description clearly indicates that one can reuse/recycle Fibra-Cel disks and that protein productivity on a support recycled according to the claimed method was comparable to that obtained on non-recycled supports (see page 15, Section 3.2). With respect to the cell lines suitable for culture on the recycled Fibra-Cel support, Applicants respectfully submit that the Office Action fails to establish that the recycled support would not be suitable for culturing hybridomas, anchorage-dependent cells or insect cells, particularly in view of the indication within the FAQ that “[t]here has been a 100% success rate with every cell line cultured on Fibra-Cel disks” (see FAQ at page 7). Applicants also note that there is no evidence of record that establishes that one skilled in the art would have been unable to reuse/recycle other supports using the claimed method.

The Office Action also argues that there is insufficient guidance and inadequate support from working examples to support a finding that the claimed invention is enabled by the as-filed specification. The Office Action argues that the specification has provided a single working example of a CHO cell and a support that is a non-woven polyester fiber bonded to a polypropylene mesh and that the recycling/reuse of other materials and culture of other cells has not been specifically exemplified. The Office Action also argues that there has been no teaching as to “the minimal structure(s)/interaction(s) by which one would determine if a cell and/or substrate as being cultivatable or the recycled substrate in an anchorage-dependent manner”.

Applicants respectfully submit that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed (see M.P.E.P. §2164.02). Indeed, the Federal Circuit has held: “The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.” *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 U.S.P.Q. 2d 1302, 1304 (Fed. Cir. 1987) (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 U.S.P.Q. 321, 325 (C.C.P.A. 1956)). Additionally, nothing more than objective enablement is required, and therefore, it is irrelevant

whether this teaching is provided through broad terminology or illustrative examples. “The test [for enablement] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed”. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982); *see also Ex parte Erlich* 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be “tedious and laborious,” such experimentation is nevertheless “routine” defining “routine” experiments as those which use known methods in combination with the variables taught in the patent to achieve the expected, specific result).

In this regard, Applicants note that one skilled in the art would have been able to determine if an anchorage-dependent cell was able to adhere to a recycled substrate made according to the claimed method (see, for example, Petti *et al.*, of record, which demonstrates the use of scanning electron microscopy and light microcopy for examining cell adhesion to a substrate). Applicants further note that one skilled in the art would have been able to ascertain if a recycled substrate could have been used for the culture of a cell through routine experiments, such as those disclosed in the as-filed specification or known to those skilled in the art (*e.g.*, by the culture of cells on the recycled substrates). Such experiments, while possibly tedious and laborious, would be considered routine by those skilled in the art. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants’ agreement with or acquiescence in the Examiner’s position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Supplemental Information Disclosure Statement